

In the Claims

Add new claims 66-102 as follows.

~~66. A nucleic acid sequence encoding P39.5 or a fragment thereof, which is selected from the group consisting of:~~

~~(a) a nucleic acid sequence encoding P39.5 or a fragment thereof, isolated from cellular materials with which it is naturally associated;~~

~~(b) a nucleic acid sequence ATCC Accession No. 98478~~

~~(c) SEQ ID NO:1 or a sequence complementary thereto;~~

~~(d) SEQ ID NO: 3 or a sequence complementary thereto;~~

~~(e) SEQ ID NO: 4 or a sequence complementary thereto;~~

~~(f) SEQ ID NO: 5 or a sequence complementary thereto;~~

~~(g) SEQ ID NO: 6 or a sequence complementary thereto;~~

~~(h) SEQ ID NO: 7 or a sequence complementary thereto;~~

~~(i) SEQ ID NO: 8 or a sequence complementary thereto;~~

~~(j) SEQ ID NO: 9 or a sequence complementary thereto;~~

~~(k) SEQ ID NO: 10 or a sequence complementary thereto;~~

~~(l) SEQ ID NO: 11 or a sequence complementary thereto;~~

~~(m) SEQ ID NO: 12 or a sequence complementary thereto;~~

~~(n) SEQ ID NO: 13 or a sequence complementary thereto;~~

~~(o) a sequence which hybridizes to any of (a) through (n) under stringent conditions;~~

~~(p) an allelic variant of any of (a) through (o);~~

~~(q) a fragment of any of (a) through (o) comprising at least 15 nucleotides in length;~~

~~(r) a deletion mutant of (a), (b), (c) (d) or (n); and~~

~~(s) a sequence encoding P39.5 or a fragment thereof fused to a sequence encoding a second protein.~~

B2
Cont.

67. A protein or polypeptide selected from the group consisting of:

- (a) an isolated P39.5 protein which is expressed *in vitro* by *Borrelia garinii* strain IP90 spirochetes, and has a relative molecular mass of 39,500 daltons;
- (b) a protein comprising the amino acid sequence of SEQ ID NO: 2;
- (c) a protein comprising the amino acid sequence of SEQ ID NO: 14;
- (d) a fragment of (a) - (c);
- (e) an analog of (a) - (c) characterized by having at least 80% homology with SEQ ID NO: 2 or 14;
- (f) a homolog of (a) - (c) characterized by having at least 80% homology with SEQ ID NO: 2 or 14.
- (g) a fusion protein comprising the amino acid sequence of SEQ ID NO: 2 or 14, or an analog, homolog or fragment thereof fused to a second protein;
- (h) a fusion protein comprising the amino acid sequence of SEQ ID NO: 2 or 14 to which are added fragments that are up to 95% identical to SEQ ID NO: 2 or 14;
- (i) a deletion protein comprising the amino acid sequence of SEQ ID NO: 2 or 14 with one or more amino acids deleted therefrom;
- (j) a protein of any of (a)-(i), which is chemically synthesized; and
- (k) a protein of any of (a)-(j) which is a recombinant protein.

68. A vector comprising a nucleic acid sequence encoding P39.5 or a fragment of claim 66 under the control of suitable regulatory sequences.

69. A host cell transformed with the vector according to claim 68.

70. A diagnostic reagent comprising a nucleic acid sequence of claim 66 and a detectable label which is associated with said sequence.

71. The antibody according to claim 16, isolated by immunizing said host with a protein or polypeptide selected from the group consisting of:

(a) an isolated P39.5 protein which is expressed *in vitro* by *Borrelia garinii* strain IP90 spirochetes, and has a relative molecular mass of 39,500 daltons;

(b) a protein comprising the amino acid sequence of SEQ ID NO: 2;

(c) a protein comprising the amino acid sequence of SEQ ID NO: 14;

(d) a fragment of (a) - (c);

(e) an analog of (a) - (c) characterized by having at least 80% homology with SEQ ID NO: 2 or 14;

(f) a homolog of (a) - (e) characterized by having at least 80% homology with SEQ ID NO: 2 or 14.

(g) a fusion protein comprising the amino acid sequence of SEQ ID NO: 2 or 14, or an analog, homolog or fragment thereof fused to a second protein;

(h) a fusion protein comprising the amino acid sequence of SEQ ID NO: 2 or 14 to which are added fragments that are up to 95% identical to SEQ ID NO: 2 or 14;

(i) a deletion protein comprising the amino acid sequence of SEQ ID NO: 2 or 14 with one or more amino acids deleted therefrom;

(j) a protein of any of (a)-(i), which is chemically synthesized; and

(k) a protein of any of (a)-(j) which is a recombinant protein.

72. The antibody according to claim 16, which is isolated by affinity purifying antiserum generated during an infection of rhesus monkeys with JD1 spirochetes using as immunoabsorbant the P39.5 protein of *B. garinii* or a fragment thereof.

73. A vaccine composition comprising an effective amount of a P39.5 protein, fusion protein or fragment of claim 67 and a pharmaceutically acceptable carrier.

74. The composition according to claim 73 wherein said fragment is selected from the group consisting of P7-1, P1-1, P3-1, P6-1, P9-1, and P12-1.

75. The composition according to claim 73 wherein said composition comprises at least one other *B. burgdorferi* antigen or fragment thereof.

76. The composition according to claim 75 wherein said other antigen is selected from the group consisting of OspA, OspB, OspC, BmpA, BmpB, BmpC, BmpD and fragments or variants thereof.

77. The composition according to claim 73 wherein said composition comprises at least one other protein or fragment thereof which has a sequence homologous to that of P39.5 or a fragment thereof.

78. The composition according to claim 73 comprising a mixture of individual proteins.

79. The composition according to claim 75 wherein said P39.5 protein or fragment and said other antigen are in the form of a fusion protein.

80. A method of vaccinating a human or animal against Lyme Disease comprising administering to said human or animal a composition comprising an effective amount of the composition of claim 73.

81. A kit for diagnosing infection with *B. burgdorferi* in a human or animal comprising a P39.5 protein or fragment thereof of claim 67.

82. A kit for diagnosing infection with *B. burgdorferi* in a human or animal comprising an anti-P39.5 antibody of claim 16.

83. A method of identifying compounds which specifically bind to P39.5 or a fragment thereof comprising the steps of contacting said P39.5 protein or fragment of claim 67 with a test compound to permit binding of the test compound to P39.5; and determining the amount of test compound which is bound to P39.5.

84. A compound identified by the method of claim 83.

85. A vector comprising a nucleic acid sequence encoding a *B. garinii* cassette string protein or fragment thereof of claim 38 under the control of suitable regulatory sequences.

86. A host cell transformed with the vector according to claim 85.

87. A method of recombinantly expressing a *B. garinii* cassette string protein or peptide fragment thereof comprising the steps of culturing a recombinant host cell transformed with a nucleic acid sequence of claim 38 encoding said protein or fragment under conditions which permit expression of said protein or peptide.

B

88. The method according to claim 87 further comprising the step of isolating said expressed protein from said cell or said cell medium.

89. The method according to claim 87 wherein said *B. garinii* cassette string protein or peptide fragment is a fusion protein or a deletion mutant protein.

90. The antibody according to claim 47, isolated by immunizing said host with the protein or a fragment thereof of the *B. garinii* cassette string selected from the group consisting of P1-1, P3-1, P6-1, P7-1, P9-1 and P12-1 or a mixture of said cassette string proteins.

B2
cont.

91. A vaccine composition comprising an effective amount of at least one *B. garinii* cassette string protein of claim 39, a fusion protein or a fragment thereof and a pharmaceutically acceptable carrier.

92. The composition according to claim 91 comprising a mixture of different *B. garinii* cassette string proteins or fragments.

93. The composition according to claim 91 comprising at least one other *B. burgdorferi* antigen or fragment thereof.

94. The composition according to claim 93 wherein said other antigen is selected from the group consisting of OspA, OspB, OspC, BmpA, BmpB, BmpC, BmpD and fragments or variants thereof.

95. The composition according to claim 91 comprising P39.5 or at least one other protein or fragment thereof which has a sequence homologous to P39.5.

B

96. A method of vaccinating a human or animal against Lyme Disease comprising administering to said human or animal a composition comprising an effective amount of the composition of claim 91.

97. A method for diagnosing Lyme borreliosis in a human or animal comprising the steps of incubating an anti-*B. garinii* cassette string protein antibody of claim 47 with a sample of biological fluids from a human or animal to be diagnosed, wherein in the presence of *B. burgdorferi* an antigen-antibody complex is formed, and subsequently analyzing said fluid sample for the presence of said complex.

98. A therapeutic composition useful in treating humans or animals with Lyme disease comprising at least one *B. garinii* cassette string protein antibody of claim 47 or fragment antibody and a suitable pharmaceutical carrier.

99. A method for treating Lyme Disease in a vertebrate host comprising administering an effective amount of a composition according to claim 98.

100. A kit for diagnosing infection with *B. burgdorferi* in a human or animal comprising a *B. garinii* cassette string protein or fragment thereof of claim 39.

101. A kit for diagnosing infection with *B. burgdorferi* in a human or animal comprising an antibody of claim 47.

102. A method of identifying compounds which specifically bind to a *B. garinii* cassette string protein or fragment thereof, comprising the steps of contacting said protein or fragment of claim 39 with a test compound to permit binding of the test compound to said *B. garinii* cassette string protein or fragment; and determining the amount of test compound which is bound to said protein or fragment.

103. A compound identified by the method of claim 102.